NOV 2 4 2000

K003028

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Osteogenics Biomedical, Inc.
3234 64th Street
Lubbock, TX 79413
(806) 792-2311

Contact Person: Chad Bartee

Date of Preparation: November 8, 2000

II. DEVICE NAME

Proprietary Name: Cytoplast™ Suture

Common Name: Non-Absorbable m-PTFE Surgical Sutures

Classification Name: Suture, Nonabsorbable, Synthetic, Polytetrafluorethylene

III. PREDICATE DEVICE

Gore-Tex™ e-PTFE Sutures; W.L Gore & Associates, Inc.

IV. DEVICE DESCRIPTION

The Cytoplast™ Suture is a nonabsorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene that has been expanded to produce a microporous structure (m-PTFE). The Cytoplast™ Suture meets all requirements in the USP 24 monograph for Nonabsorbable Surgical Sutures. The suture is undyed and contains no additives. The Cytoplast™ Suture is supplied sterile with attached standard surgical needles in a variety of sizes.

V. INTENDED USE

The Cytoplast™ Suture is intended for use in the approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes. The intended use of the predicate device, Gore-Tex™ e-PTFE Sutures, is broader, including cardiovascular surgery and dura mater repair. However, Osteogenics Biomedical has limit the intended use to the dental surgical market in which it operates.

VI. COMPARISON TO PREDICATE DEVICE

	Cytoplast™ m-PTFE Suture	Predicate Device
Intended Use:	Approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.	Soft tissue approximation and/or ligation, including use in cardiovascular surgery and dura mater repair.
Suture material:	Polytetrafluoroethylene (100%); expanded	Polytetrafluoroethylene (100%); expanded
Suture Characteristics:	Not absorbed and no significant changes known to occur *in vivo*.	Not absorbed and no significant changes known to occur *in vivo*.
How Supplied:	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.
Use (single, reusable, disposable)	Single Use Only.	Single use Only.
Suture Diameter Suture Length Needle Attachment Strength Knot Pull Tensile Strength	Meets U.S.P. requirements.	Differs from U.S.P. requirements in diameter and knot-pull tensile strength.
Packaging	Dry packaged in paper/ polyester-polypropylene tear-open pouch.	Same or equivalent manner.

Based on this comparison, Osteogenics Biomedical, Inc. concludes that the Cytoplast™ Suture is safe and effective for its intended use and performs at least as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Osteogenics Biomedical, Inc.
c/o Mr. Richard A. Hamer
Richard Hamer Associates, Inc.
6401 Meadows West Drive
Fort Worth, Texas 76132

Re: K003028
Trade Name: Osteogenics Biomedical, Inc. Cytoplast™ Sutures
Regulatory Class: II
Product Code: NBY
Dated: September 27, 2000
Received: September 28, 2000

Dear Mr. Bartee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhorn

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003028

510(k) Number (if known): _____

Device Name: Cytoplast™ Sutures

Indications for Use:

A removable, nonabsorbable suture for approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

for Mark N Milkins

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003028